DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on 06/06/2008 with the cancellation of claims 2, 3, 11 and 13, the amendment of claims 1, 4-10 and 12 and newly added claim 17.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

This application contains claims 14-16 which are drawn to an invention nonelected with traverse in the reply filed on 07/17/2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1, 4-10, 12 and 17 are under examination.

Specification

The abstract of the disclosure is objected to because the amendment to the abstract introduces new matter for the newly added terms: "juice from a grape" and "*Musa* plants". Please see below for further clarification. Correction is required. See MPEP § 608.01(b).

The amendment filed 06/06/2008 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added

material which is not supported by the original disclosure is as follows: "juice from a grape" and "*Musa* plants". Applicant originally disclosed in the claims and in the specification, as originally filed, a medicinal product comprising extracts of prunus armeniaca, cocos nucifera, humulus lupulus, germinated barley, mycete, the liquid obtained from alcoholic fermentation of the grape juice of gravevines, musaze and rubus leaves. There was no description in the originally filed specification or in the original claims that demonstrated that Applicant was in possession of the newly added species "juice from a grape" and "*Musa* plants".

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

Claims 1, 4-10, 12 and 17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Newly applied as necessitated by amendment.

In the amended claim 1, Applicant claims, "a therapeutically effective amount of liquid obtained from alcoholic fermentation of juice from a grape" and "a therapeutically effective amount of an extract of *Musa* plants", thereby introducing two new species that were not previously disclosed in the originally filed specification and claims, which is considered to be new matter. Insertion of the above mentioned claim limitation has no

support in the as-filed specification. The insertion of the limitation is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited genus which would show possession of the concept for a composition comprising "a therapeutically effective amount of liquid obtained from alcoholic fermentation of juice from a grape" and "a therapeutically effective amount of an extract of *Musa* plants".

The originally filed specification disclosed a medicinal product comprising extracts of prunus armeniaca, cocos nucifera, humulus lupulus, germinated barley, mycete, the liquid obtained from alcoholic fermentation of the grape juice of gravevines, musaze and rubus leaves. However, the originally filed specification did not provide a description in the originally filed specification or in the original claims that demonstrated that Applicant was in possession of the newly added species "juice from a grape" and "*Musa* plants". This is not sufficient support for the new limitations: "a therapeutically effective amount of liquid obtained from alcoholic fermentation of juice from a grape" and "a therapeutically effective amount of an extract of *Musa* plants". This is a matter of written description, not a question of what one of skill in the art would or would not have known.

The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Declarations and new references cannot demonstrate the possession of a concept after the fact. Thus, the insertion of the above mentioned claim-limitation is considered to be the insertion of new matter for the above reasons.

As the above-mentioned claim limitation could not be found in the present specification, the recitation of the claim limitation is deemed new matter; and, therefore it must be omitted from the claim language, unless Applicant can particularly point to the specification for literal support.

Claims 1, 4-10, 12 and 17 are also rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Enablement is considered in view of the *Wands* factors (MPEP 2164.01(A)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, state of the art predictability of the art and the amount of experimentation necessary. All of the Wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the Invention: The claims are drawn to a medicinal composition for treating Acquired Immune Deficiency, cancer and neurological diseases comprising a therapeutically affective amount of an extract of *Prunus armeniaca*, a therapeutically affective amount of an extract of *Cocos nucifera*, a therapeutically affective amount of an extract of *Humulus lupulus*, a therapeutically affective amount of an extract of germinated barley, a therapeutically affective amount of an extract of mycete, a

therapeutically effective amount of liquid obtained from alcoholic fermentation of juice from a grape, a therapeutically effective amount of an extract of *Musa* plants; and a therapeutically effective amount of an extract of *Rubus* leaves.

The nature of the invention is complex in that the claims are drawn to a medicinal composition for treating Acquired Immune Deficiency, cancer and neurological diseases comprising a therapeutically affective amount of an extract of *Prunus armeniaca*, a therapeutically affective amount of an extract of *Cocos nucifera*, a therapeutically affective amount of an extract of *Humulus lupulus*, a therapeutically affective amount of an extract of germinated barley, a therapeutically affective amount of an extract of mycete, a therapeutically effective amount of liquid obtained from alcoholic fermentation of juice from a grape, a therapeutically effective amount of an extract of *Musa* plants; and a therapeutically effective amount of an extract of *Rubus* leaves. However, first of all, it is presumed that Applicant means Acquired Immune Deficiency Syndrome rather than simply Acquired Immune Deficiency. Secondly, Applicant is claiming that any type of cancer may be treated with this composition. Finally, Applicant is claiming that any type of neurological disorder is treatable with this composition. With regards to the composition itself, Applicant envisions that any type of extract (eg. polar, non-polar, aqueous or specific compounds, since an extract includes all of these types of extracts) from each of the abovementioned plants is useful and that any genus and specie of mycete (please note that mycete is a generic term for fungi) and any specie of *Musa* and *Rubus* plant may be used.

Breadth of the Claims: The claims are broad in that the claims recite a medicinal composition for treating Acquired Immune Deficiency Syndrome, cancer and neurological diseasess comprising a therapeutically affective amount of an extract of *Prunus armeniaca*, a therapeutically affective amount of an extract of *Cocos nucifera*, a therapeutically affective amount of an extract of *Humulus lupulus*, a therapeutically affective amount of an extract of germinated barley, a therapeutically affective amount of an extract of mycete, a therapeutically effective amount of liquid obtained from alcoholic fermentation of juice from a grape, a therapeutically effective amount of an extract of *Musa* plants; and a therapeutically effective amount of an extract of *Rubus* leaves. The complex nature of the subject matter of this invention is greatly exacerbated by the breadth of the claims, as set forth above.

Guidance of the Specification and Existence of Working Examples: The specification envisions that by administering a medicinal composition comprising a therapeutically affective amount of an extract of *Prunus armeniaca*, a therapeutically affective amount of an extract of *Cocos nucifera*, a therapeutically affective amount of an extract of *Humulus lupulus*, a therapeutically affective amount of an extract of germinated barley, a therapeutically affective amount of an extract of mycete, a therapeutically effective amount of liquid obtained from alcoholic fermentation of juice from a grape, a therapeutically effective amount of an extract of *Musa* plants; and a therapeutically effective amount of an extract of *Rubus* leaves, that the composition will treat Acquired Immune Deficiency Syndrome, cancer and neurological diseases.

However, no working examples are provided with regard to treating Acquired Immune Deficiency Syndrome, cancer or neurological diseases by administering a medicinal composition comprising a therapeutically affective amount of an extract of *Prunus armeniaca*, a therapeutically affective amount of an extract of *Cocos nucifera*, a therapeutically affective amount of an extract of *Humulus lupulus*, a therapeutically affective amount of an extract of germinated barley, a therapeutically affective amount of an extract of mycete, a therapeutically effective amount of liquid obtained from alcoholic fermentation of juice from a grape, a therapeutically effective amount of an extract of *Musa* plants; and a therapeutically effective amount of an extract of *Rubus* leaves. Furthermore, no examples are provided with regards to the administration of a medicinal composition comprising a therapeutically affective amount of an extract of *Prunus armeniaca*, a therapeutically affective amount of an extract of *Cocos nucifera*, a therapeutically affective amount of an extract of *Humulus lupulus*, a therapeutically affective amount of an extract of germinated barley, a therapeutically affective amount of an extract of mycete, a therapeutically effective amount of liquid obtained from alcoholic fermentation of juice from a grape, a therapeutically effective amount of an extract of *Musa* plants; and a therapeutically effective amount of an extract of *Rubus* leaves to any subject and no tests have been conducted, either *in vitro* or *in vivo* to demonstrate that this composition is capable of performing the functions claimed.

Please note that Acquired Immune Deficiency Syndrome requires administration of an antiretroviral medicine and that in order to show that the composition is capable of treating Acquired Immune Deficiency Syndrome, and the instantly claimed medicinal

composition would have to demonstrate antiretroviral properties through extensive testing. With regards to treating cancer, there are certain types of cancer that are not treatable by drugs, such as lung cancer, and, as with all cancers, success and type of treatment depend on a variety of factors, such as histopathologic (diseased tissue) type of tumor present and the stage at which the cancer is detected. Therefore, testing would need to be conducted to demonstrate, at the very least, the effectiveness of the claimed composition on specific cancer cell lines, *in vitro*, or on specific types of cancer, *in vivo*. Finally, with regards to neurological disorders, there are many neurological disorders that are not treatable, like Alzheimer's disease, Creutzfeldt-Jakob Disease and Parkinson's Disease, to name a few. Again, testing would need to be conducted to demonstrate that the claimed composition is capable of treating these diseases, and based upon what was known in the art at the time the invention was made, it is unlikely that this composition is capable of treating neurological diseases, particularly the ones mentioned herein.

Predictability and State of the Art: The state of the art at the time the invention was made was unpredictable and underdeveloped. Kubic (U, U.S. Food and Drug Administration: New Ways to Prevent and Treat AIDS) teaches that the following class of drugs have been approved for treatment of people suffering from AIDS: protease inhibitors, nucleoside analogs, which included Retrovir (zidovudine, also known as AZT), Videx (didanosine, or ddI), Hivid (zalcitabine, or ddC), Zerit (stavudine, or d4t), and Epivir (lamivudine, or 3TC), non-nucleoside reverse transcriptase inhibitors and a second drug in this class, Rescriptor (delavirdine). Viramune was approved for use in

combination with nucleoside analogs to treat adults with HIV infection who have experienced clinical and/or immunological deterioration. Rescriptor was approved for use in combination with appropriate anti-HIV medicines for patients with HIV infection when treatment is warranted. Kubic further teaches that FDA approved Combivir, an AZT-and-3TC combination medicine for AIDS and HIV infection. Kubic further teach the protease inhibitors--Invirase and Fortovase (saquinavir), Norvir (ritonavir), Crixivan (indinavir), and Viracept (nelfinavir)--inhibit replication of HIV in a similar way as nucleoside analogs, but are active at different points in the replication process. Kubic further teaches that tested alone or in combination with the nucleoside analogs, the three protease inhibitors markedly reduced the viral load and increased the number of CD4 cells, which sharply declines in HIV infection and AIDS. Kubic further teaches that the U.S. Food and Drug Administration does not support unapproved therapies for the treatment of AIDS. Therefore, only the approved retroviral drugs have been shown to be effective in treating AIDS.

Lung Cancer: Therapy (V) teaches that the way that lung cancer is currently treated depend on the stage at which the cancer is diagnosed, and that the only treatments currently used are radiation therapy or surgery. Lung Cancer: Therapy further teaches that overall, fewer than 10% of people with primary lung cancer are alive 5 years after diagnosis, but 5-year survival rates may be as high as 35 to 40% among patients who undergo surgical resection for cancer that has not spread beyond the lung.

MayoClinic: Creutzfelt-Jakob disease (Mad cow disease) (W, http://www.mayoclinic.com/health/creutzfeldt-jakob-disease/DS00531, July 31, 2008) teaches that no effective treatment exists for Creutzfelt-Jakob disease or any of its variants, despite testing of a number of drugs.

Thus, while the claim-designated method may be useful for providing such an effect, Applicant does not disclose a method of treating Acquired Immune Deficiency, cancer and neurological diseases comprising administering a medicinal composition comprising a therapeutically affective amount of an extract of *Prunus armeniaca*, a therapeutically affective amount of an extract of *Cocos nucifera*, a therapeutically affective amount of an extract of *Humulus lupulus*, a therapeutically affective amount of an extract of germinated barley, a therapeutically affective amount of an extract of mycete, a therapeutically effective amount of liquid obtained from alcoholic fermentation of juice from a grape, a therapeutically effective amount of an extract of *Musa* plants; and a therapeutically effective amount of an extract of *Rubus* leaves.

Amount of Experimentation Necessary: The quantity of experimentation necessary to carry out the claimed invention is high, as the skilled artisan could not rely on the prior art or instant specification to teach how to use a medicinal composition comprising a therapeutically affective amount of an extract of *Prunus armeniaca*, a therapeutically affective amount of an extract of *Cocos nucifera*, a therapeutically affective amount of an extract of *Humulus lupulus*, a therapeutically affective amount of an extract of germinated barley, a therapeutically affective amount of an extract of mycete, a therapeutically effective amount of liquid obtained from alcoholic fermentation

of juice from a grape, a therapeutically effective amount of an extract of *Musa* plants; and a therapeutically effective amount of an extract of *Rubus* leaves wherein the composition treats Acquired Immune Deficiency Syndrome, cancer and neurological disease in humans. In order to carry out the claimed invention, one of ordinary skill in the art would have to identify a medicinal composition comprising a therapeutically affective amount of an extract of *Prunus armeniaca*, a therapeutically affective amount of an extract of *Cocos nucifera*, a therapeutically affective amount of an extract of *Humulus lupulus*, a therapeutically affective amount of an extract of germinated barley, a therapeutically affective amount of an extract of mycete, a therapeutically effective amount of liquid obtained from alcoholic fermentation of juice from a grape, a therapeutically effective amount of an extract of *Musa* plants; and a therapeutically effective amount of an extract of *Rubus* leaves that can be administered in a therapeutically effective dose with an acceptable level of side-effects.

In view of the breadth of the claims and the lack of guidance provided by the specification as well as the unpredictability of the art, the skilled artisan would have required an undue amount of experimentation to make and/or use the claimed invention. Therefore, claims 1, 4-10, 12 and 17 are not considered to be fully enabled by the instant specification.

Any previous rejections not addressed above have been overcome by Applicant's amendment to the claims and have, therefore, been withdrawn.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy L. Clark whose telephone number is (571)272-1310. The examiner can normally be reached on Monday to Friday between 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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